

AUG 27 1996

510(k) Summary**Elecsys® CalCheck™ FT4**

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- Introduction** According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
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- 1) Submitter name, address, contact** Boehringer Mannheim Corporation
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- Date Prepared: August 12, 1996
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- 2) Device name** Proprietary name: Elecsys CalCheck FT4
- Common name: Calibration Verification Material
- Classification name: Single (specified) analyte controls (assayed + unassayed)
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- 3) Predicate device** We claim substantial equivalence to the Tosoh Medic AIA-Pack HCG Calibration Verification Test Set, K924862. The intended use for both products is to verify the calibration curve of automated immunoassay analyzers
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- 4) Device Description** The Elecsys CalCheck FT4 is a three level single analyte set of lyophilized, human based materials. After reconstitution they are assayed in triplicate and the results are compared to the target values.
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- 5) Intended use** Elecsys CalCheck FT4 is intended for use in the quantitative verification of the calibration curve established by the Elecsys FT4 reagents and calibrators on Elecsys 1010 or 2010 immunoassay analyzers.

510(k) Summary, Elecsys® CalCheck™ FT4, Continued

**6) Comparison
to predicate
device**

The Boehringer Mannheim Elecsys CalCheck FT4 is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed Tosoh Medics AIA-Pack HCG Calibration Verification Test Set, K924862.

The intended use of both the Elecsys CalCheck FT4 and the predicate device are the same in that they are intended to be used for the calibration verification for their labeled analytes on automated immunoassay analyzers.